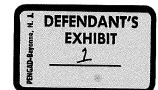
UNITED STATES DISTRICT COURT

for the

| District of | Massachusetts |
|---|--|
| In re: New England Compounding Pharmacy, Inc. Plaintiff v. Defendant |)) Civil Action No. MDL 1:13-md-02419) (If the action is pending in another district, state where:) |
| SUBPOENA TO TESTIFY AT A | A DEPOSITION IN A CIVIL ACTION |
| To: Howell Allen Clinic, P.C., via Registered Agent, Gre 37203-2023 | egory B. Lanford, 2011 Murphy Ave., Ste. 301, Nashville, TN |
| deposition to be taken in this civil action. If you are an o | ear at the time, date, and place set forth below to testify at a organization that is <i>not</i> a party in this case, you must designate esignate other persons who consent to testify on your behalf himent: |
| Place: 2011 Murphy Ave., Ste. 301, Nashville, TN 3720 | 03-2023 Date and Time: 07/29/2013 9:00 am |
| | Stenographically and/or Videographically also bring with you to the deposition the following documents, permit their inspection, copying, testing, or sampling of the |
| The provisions of Fed. R. Civ. P. 45(c), relating to 45 (d) and (e), relating to your duty to respond to this sub attached. Date: 7-8-13 CLERK OF COURT | to your protection as a person subject to a subpoena, and Rule oppoena and the potential consequences of not doing so, are |
| Signature of Clerk or Deputy | OR Clerk Attorney's signature |
| The name, address, e-mail, and telephone number of the a Plaintiffs' Steering Committee J. Gerard Stranch, IV, Branstetter, Stranch, and Jennings, | , who issues or requests this subpoena, are: |



AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. MDL 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

| as received by me on (da | · · | | |
|--------------------------|---|---|---|
| ☐ I served the su | opoena by delivering a copy to the nan | ned individual as follows: | |
| | | on (date) ; or | |
| ☐ I returned the s | ubpoena unexecuted because: | | |
| | | States, or one of its officers or agents, I d the mileage allowed by law, in the am | |
| \$ | • | | |
| y fees are \$ | for travel and \$ | for services, for a total of \$ | 0.00 |
| I declare under pe | nalty of perjury that this information is | s true. | |
| e: | | Server's signature | *************************************** |
| | | Server & digname | |
| | | Printed name and title | |
| | | | |
| | | Server's address | |

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

- (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction which may include lost earnings and reasonable attorney's fees on a party or attorney who fails to comply.
 - (2) Command to Produce Materials or Permit Inspection.
- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- (A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

- (d) Duties in Responding to a Subpoena.
- (1) Producing Documents or Electronically Stored Information.

 These procedures apply to producing documents or electronically stored information:
- (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Case 1:13-md-02419-RWZ Document 304-1 Filed 07/16/13 Page 4 of 24

ORIGINAL DOCUMENT PRINTED ON CHEMICAL REACTIVE PAPER WITH MICROPHINTED BORDER

BRANSTETTER, STRANCH & JENNINGS, PLLC

29062

HOWAL

Howell Allen Clinic

07/08/13

29062

\$40.00

Invoice # **MENINGITIS** <u>Date</u>

07/08/13

Our Ref # 33717

Reference

WITNESS FEE (#2) MENINGITIS, 12-496

Invoice Amt

\$40.00

BRANSTETTER, STRANCH & JENNINGS, PLLC

ATTORNEYS AT LAW **OPERATING ACCOUNT** 227 SECOND AVENUE NORTH, 4TH FLOOR NASHVILLE, TENNESSEE 37201-1631

Zinnacle

NUMBER

29062

87-863/640

29062

HOWAL

DATE

AMOUNT

07/08/13

\$40,00

BRANSTETTER, STRANCH & JENNINGS, PLLC

29062

Nashville, TN 37203

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BRANSTETTER, STRANCH & JENNINGS, PLLC

29062

HOWAL

PAY TO THE

ORDER

Howell Allen Clinic

07/08/13

\$40.00

Invoice # **MENINGITIS**

Forty and NO/100 Dollars

Howell Allen Clinic 2011 Murphy Ave # 401

07/08/13

Our Ref # 33717

Reference

WITNESS FEE (#2) MENINGITIS, 12-496

Invoice Amt

\$40.00

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

| IN RE: NEW ENGLAND) | |
|---------------------------------------|---------------------------|
| COMPOUNDING PHARMACY, INC.) | MDL No. 1:13-md-02419 |
| PRODUCTS LIABILITY LITIGATION) | |
| | Hon. F. Dennis Saylor, IV |
| This Document Relates To: All Cases) | |
|) | |

NOTICE OF TAKING ORAL DEPOSITION OF DESIGNATED REPRESENTATIVE(S)

Please take notice that on July 26, 2013 beginning at 9:00 a.m. at the offices of Howell Allen Clinic, PC, 2011 Murphy Ave., Ste 301, Nashville, TN 37203, Nashville, TN 37205-2221 the deposition of a designated corporate representative will be taken upon oral examination by one or more attorneys of the Plaintiffs' Steering Committee in the pending MDL, pursuant to Rule 30 of the Federal Rules of Civil Procedure for the purpose of discovery or for use as evidence in this action, and before an officer authorized by law to administer oaths. The deposition shall be recorded stenographically and/or videographically.

PLEASE TAKE FURTHER NOTICE that pursuant to Rules 30 and 34 of the Federal Rules of Civil Procedure, the non-party deponent(s) shall produce at the deposition the documents identified in Exhibit B attached to the subpoena contemporaneously served herewith.

<u>Duty to designate.</u> By designating a representative, the organization indicates its representative has the authority to speak on its behalf about the matters listed in this deposition notice – not only to facts, but also to subject beliefs and opinions.¹

<u>Duty to substitute</u>. If it becomes clear that the chosen representative is unable to respond to questions on the matters for which he or she has been designated, the organization must immediately provide a substitute knowledgeable witness. This is required even if the initial designation was made in good faith.²

<u>Duty to prepare</u>. The testimony elicited in the deposition represents the organization's knowledge, not the individual deponent's knowledge. The organization must conduct a thorough investigation in response to the deposition notice and must prepare any witness to testify to all matters "known or reasonably available to the organization." Therefore, if the organization's designee is not knowledgeable about the matters specified in the deposition notice, it must nonetheless prepare such designee to give knowledgeable, binding answers.³

"Reasonably available" information includes all documents that the organization has the authority, legal right, or practical ability to obtain. An inadequately prepared designated witness will amount to an impermissible refusal to answer and a sanctionable failure to appear. 4

¹ Lapenna v. Upjohn Co., 110 F.R.D. 15, 20 (E.D. Pa. 1986); See also Alexander v. Fed. Bureau of Investigation, 186 F.R.D. 148, 151-52 (D.D.C. 1999); Mitsui & Co. v. Puerto Rico Water Res. Autho.,93 F.R.D. 62, 66-67 (D.P.R. 1981).

² See Marker v. Union Fidelity Life, 125 F.R.D. 121, 126 (M.D.N.C. 1989).

³ United States v. Taylor, 166 F.R.D. 356, 361 (M.D.N.C. 1996).

⁴ Prokosch v. Catalina Lighting, Inc., 193 F.R.D. 633, 637 (D. Minn. 2000) (citing Lumber v. PPG Industries, Inc., 168 F.R.D. 641, 643 n. 1 (D. Minn. 1966); See Black Horse Lane Assoc., L.P. v. Down Chem. Corp., 228 F. 3d 275, 303-04 (3d Cir. 2000); Resolution Trust Corp. v. S. Union Co., 985 F. 2d 196,

Scope of inquiry The description contained in the deposition notice simply identifies the minimum to which a witness must be prepared to testify. If an examining party asks questions outside the scope of the matters described in the notice, the general deposition rules govern.

DESIGNATION OF TESTIMONY AND PRODUCTION OF DOCUMENTS

The designated matters upon which examination is requested are as follows:

- 1. To provide testimony regarding those individuals involved in the production of documents.
- 2. To provide testimony regarding the efforts made and the time expended in the production of documents.
- To provide testimony regarding the methods of search and methods of production of documents produced.
- 4. To provide testimony regarding the authenticity of documents.
- 5. To provide testimony regarding the methods of storage, entry and use of computer data and the method by which it has been produced.
- 6. To provide testimony regarding the location and methods of storage of corporate documents.
- 7. To provide testimony regarding the existence of documents.
- 8. To provide testimony regarding the electronic creation, duplication and/or storage of the documents.

^{197 (5&}lt;sup>th</sup> Cir. 1993); *Taylor*, 166 F.R.D. at 363; *Marker v. Union Fidelity Life Ins. Co.*, 125 F.R.D. 121, 126 (M.D.N.C. 1989).

- 9. To provide testimony regarding any and all document retention/destruction policies that would relate to any of the documents.
- 10. To provide testimony regarding the searchability of databases for the extraction of information.
- 11. To provide testimony regarding the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy Inc. ("NECP") during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescription order forms, NECP charges for MPA (before and after any discounts applied).
- 12. To provide testimony regarding the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility, or manufacturer other than NECP, during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life,

- expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.
- 13. To provide testimony regarding procurement of cardioplegic solution NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.
- 14. To provide testimony regarding the procurement of ophthalmic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.
- 15. To provide testimony regarding the procurement of preservative-free saline solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life,

- expiration dates, and requirements and instructions for shipment and/or storage.
- 16. To provide testimony regarding procurement of methylprednisolone acetate ("MPA") and any other product from New England Compounding Pharmacy, Inc. ("NECP") during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the amount you paid for the steroid preparation, any discounts you received in purchasing the preparations, applicable warranties, shelf life, expiration dates, prescription order forms, any other account information, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.
- 17. To provide testimony regarding the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth and identification of product administered.
- 18. To provide testimony regarding the identity of the name, address, phone number, and social security number of any patient that received any product manufactured by NECP from 2011-2012 and sufficient documents to identify the specific NECP product received by the patient.
- 19. To provide testimony regarding the communications (written or otherwise) between the Howell Allen Clinic, P.C. ("Healthcare Provider"), its employees

- and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012.
- 20. To provide testimony regarding information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information)
- 21. To provide testimony regarding communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the two-year period immediately preceding October 6, 2012, including but not limited to any microbiology reports or certificates of analysis.
- 22. To provide testimony regarding information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

- 23. To provide testimony regarding marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.
- 24. To provide testimony regarding agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.
- 25. To provide testimony regarding recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.
- 26. To provide testimony regarding any investigation or inquiry the Healthcare Provider performed related to NECP's compliance with UPS 797.
- 27. To provide testimony regarding regarding the Healthcare Provider's and/or NECP's compliance with Tenn. Comp. R. & Regs. R. § 1140-01-.08.
- 28. To provide testimony regarding the Health Provider's compliance Tenn. Comp. R. & Regs. R. § 1140-01-.04.
- 29. To provide testimony relating to the Healthcare Provider's compliance with Tenn. Comp. R. & Regs. R. § 1140-01.05 for all NECP products dispensed by the Healthcare Provider.
- 30. To provide testimony regarding policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products

liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011 and 2012.

- 31. To provide testimony regarding the ownership and management of the Healthcare Provider's operations.
- 32. To provide testimony regarding the identity of physicians and/or pharmacists that prescribed and/or dispensed NECP products to patients.
- 33. To provide testimony regarding the identity of any persons or entities that you believe may be liable, either through principals of comparative fault, joint tortfeasor, or any other related legal principal, for any injury suffered by any of the Healthcare Provider's patients as a result of exposure to NECP products.
- 34. To provide testimony regarding the identity of any expert, outside consultant, physician, and/or pharmacists that reviewed or approved the Healthcare Provider's use of NECP products.
- 35. To provide testimony regarding the decision of the Healthcare Provider to use NECP products.
- 36. To provide testimony on the identity of individuals who were responsible for the purchase, receipt, storage, and/or maintenance of NECP products for the two year period prior to October 6, 2012.
- 37. To provide testimony regarding the relationship between the Healthcare Provider, St. Thomas Outpatient Neurological Center ("STOPNC"), and the

- St. Thomas Health Network St. Thomas Health Network (which includes, but is not limited to, St. Thomas Network, St. Thomas Health, and St. Thomas Hospital, collectively "St. Thomas Health Network").
- 38. To provide testimony regarding any transfer of pharmaceuticals, medical equipment, office equipment, office supplies, computers, hardware, and/or software between the Healthcare Provider, STOPNC, and/or St. Thomas Health Network.
- 39. To provide testimony regarding any decisions, concerning patient care, employee relations, procurement of pharmaceuticals or medical equipment, where the Healthcare Provider received advice or direction from STOPNC and/or St. Thomas Health Network.
- 40. To provide testimony regarding any contracts and/or agreements between the Healthcare Provider, STOPNC, and/or the St. Thomas Health Network.

Exhibit B to Subpoena

- 1. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescription order forms, NECP charges for MPA (before and after any discounts applied).
- 2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.
- 3. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.
- 4. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.
- 5. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.

- 6. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other product from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the amount you paid for the steroid preparation, any discounts you received in purchasing the preparations, applicable warranties, shelf life, expiration dates, prescription order forms, any other account information, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.
- 7. Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth and identification of product administered.
- 8. Sufficient documents to identify the name, address, phone number, and social security number of any patient that received any product manufactured by NECP from 2011-2012 and sufficient documents to identify the specific NECP product received by the patient.
- 9. Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between Howell Allen Clinic, P.C. ("Healthcare Provider"), its employees and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012.
- 10. Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information)
- Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the two-year period immediately preceding October 6, 2012, including but not limited to any microbiology reports or certificates of analysis.
- 12. Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

- 13. Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.
- 14. Any and documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.
- 15. Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.
- 16. Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.
- 17. Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to NECP's compliance with UPS 797.
- 18. Any and all documents regarding the Healthcare Provider's and/or NECP's compliance with Tenn. Comp. R. & Regs. R. § 1140-01-.08.
- 19. Any and all documents maintained by the Healthcare Provider related to Tenn. Comp. R. & Regs. R. § 1140-01-.04.
- 20. Any and all documents maintained by the Healthcare Provider evincing its compliance with Tenn. Comp. R. & Regs. R. § 1140-01.05 for all NECC products dispensed by the Healthcare Provider.
- 21. Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011 and 2012.
- 22. Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011 and 2012.
- 23. Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011 and 2012.

- 24. Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.
- 25. Any and all organizational charts maintained by the Healthcare Provider and/or any documents listing directors, officers, employees, and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.
- Any and all documents showing the relationship between the Healthcare Provider and the St. Thomas Health Network (which includes, but is not limited to, St. Thomas Network, St. Thomas Health, and St. Thomas Hospital, collectively "St. Thomas Health Network"), and the St. Thomas Outpatient Neurosurgical Center.
- 27. Any and all documents showing the names of physicians and/or pharmacists that prescribed and/or dispensed NECP products to patients.
- 28. Any and all communications between the Healthcare Provider and the St. Thomas Health Network related to NECP.
- 29. Any and all communications between the Healthcare Provider and the St. Thomas Outpatient Neurosurgical Center related to NECP.
- 30. Any and all communications between the Healthcare Provider and Michael O'Neil or any other consultant who provided advice or services related to the Healthcare Provider's provision of NECP products.
- 31. Any and all documents related to any decisions, concerning patient care, employee relations, procurement of pharmaceuticals or medical equipment, where the Healthcare Provider provided to or received advice or direction from St. Thomas Outpatient Neurosurgical Center and/or the St. Thomas Health Network.
- 32. Any and all documents related to any transfer of pharmaceuticals, medical equipment, office equipment, office supplies, computers, hardware, and/or software between the Healthcare Provider, St. Thomas Health Network, and/or the St. Thomas Outpatient Neurosurgical Center.
- 33. Any and all board minutes or notes of board minutes that relate to St. Thomas Outpatient Neurosurgical Center.

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

MDL No. 2419

Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

ORDER GRANTING PLAINTIFFS LEAVE TO SERVE SUBPOENAS AND QUALIFIED PROTECTIVE ORDER REGARDING PROTECTION OF HEALTH INFORMATION

WHEREAS, the Court recognizes that protected health information may be produced in response to subpoenas issued by parties in the MDL;

WHEREAS, nothing in this order shall deprive a subpoena recipient of the opportunity to object to requests to produce such protected information;

WHEREAS, the Court desires to establish an up-front process for the production of any such protected health information in compliance with applicable federal and state law.

IT IS HEREBY ORDERED that "Personal Health Information," and "individually identifiable health information" protected under the Health Insurance Portability and Accountability Act of 1996 (hereinafter "HIPAA") (42 USC §1320d et seq.) and the regulations promulgated thereunder (45 CFR §§160, 164 et seq.), shall only be disclosed as follows:

1. Healthcare facilities and/or providers that have examined, tested or treated patients who have been identified as recipients of one or more of New England Compounding Pharmacy, Inc. ("NECC") solutions, medications or compounds, shall produce protected health information pursuant to this order and a subpoena issued by Plaintiffs.

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- 2. The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.
- 3. All protected health information produced pursuant to this order shall be produced in electronic or hard copy format only to a third party vendor (the "Vendor") to be selected jointly by the Plaintiffs' Steering Committee, the chapter 11 trustee appointed in NECC's chapter 11 case (the "Trustee"), and the Official Committee of Unsecured Creditors appointed in NECC's chapter 11 case (the "Official Committee"), after meeting and conferring.
- 4. The Vendor shall hold such protected health information in the strictest confidence and shall not release such information to any other person or entity until further order of this Court.
- 5. In the case of electronic data, the Vendor shall maintain the obtained protected health information on a server that is housed in a data center secured and hardened against unauthorized access or download, including unauthorized access via the Internet or any wireless device. The information obtained in electronic form pursuant to the subpoenas shall be loaded to a database that is password-protected and encrypted. The Vendor shall maintain similar protections against unauthorized access to any protected information produced in hard copy format.

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- 6. The documents, data, or other information produced pursuant to the subpoenas and this Order shall be provided for the sole purposes of (i) investigating, litigating and resolving potential claims involved in this litigation; (ii) litigating and resolving potential claims in the chapter 11 case of NECC (the "Chapter 11 Case"); and (iii) the administration of the Chapter 11 Case, and not for any other purpose. In the event Defendants wish to use documents, data or other information produced pursuant to the subpoenas and this Order, they may seek permission of the Court to do so.
- 7. Within thirty (30) days of entry of this Order, the Plaintiffs' Steering Committee, Defense Liaison counsel, the Trustee, and the Official Committee shall propose to the Court a protocol for sharing the protected health information housed by the Vendor with necessary parties approved by the Court, including without limitation, their experts for purposes of providing expert reports and or analysis. That proposed protocol will also seek to ensure that any such protected health information shared with other parties or experts is provided a level of security against unauthorized disclosure that is compliant with HIPPA.
- 8. Nothing in this Order authorizes direct communications between defendants, their counsel or other agents or representatives and the patients' healthcare providers providing disclosure pursuant to this Order, nor does it bar such communications.
- 9. The Vendor shall maintain the information received in connection with the subpoenas until the later of (i) one (1) year after the resolution of this matter or (ii) one (1) year after the resolution of all claims in NECC's chapter 11 case (in either case, the "Retention Period"), or as otherwise ordered by the Court. At the end of the Retention Period, or as ordered by the Court, it shall destroy any and all originals and copies of the information obtained, including electronic and hard copies.

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10. Plaintiffs' Counsel are authorized to serve subpoenas issued by this Court on the

entities listed in NECC's Customer list located at:

http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf as well as

Pharmacy Support, Inc., CuraScript, Inc., and Clint Pharmaceuticals.

11. All subpoenaed entities that provide requested information shall be deemed to fall

within the safe harbor of HIPAA for court-ordered production of personal health information, 45

C.F.R. § 164.512(e)(1), and shall have no liability under HIPAA or any other federal or state

statute, regulation, or other requirement related to protected health information, for supplying

patient or member information to the Vendor.

12. The Vendor shall not be deemed to be a guarantor of the completeness and

accuracy of the data provided to it and shall have the right to rely in good faith upon the

information provided by any subpoenaed entity.

13. The subpoenaed entities are to use their best effort to supply the requested

information.

14. The subpoenaed entities must produce the requested information to the Vendor

within 30 days of receipt of the subpoena.

15. A copy of this Order shall be appended to the subpoenas.

SO ORDERED.

Dated this 21st day of June , 2013.

/s/ F. Dennis Saylor

F. Dennis Saylor, IV

United States District Judge

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

MDL No. 2419

Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

ORDER ON **CENTRAL ENFORCEMENT OF SUBPOENAS**

WHEREAS the Plaintiffs' Steering Committee has advised the Court that it intends to issue subpoenas to:

- Pain clinics, hospitals, and other entities or individuals who purchased NECC's methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution:
- Vendors and contractors who worked on or were responsible for the conditions of the NECC facility;
- Vendors who conducted sterility or other testing of NECC's products or equipment used to make the products; and
- Suppliers who provided the raw materials used to create methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution.

WHEREAS the Court has the authority to enforce subpoenas issued out of the MDL;

WHEREAS the Court finds that central enforcement of these subpoenas will promote efficiency and the interests of justice;

IT IS HEREBY ORDERED

- 1. This Court will centrally enforce subpoenas issued out of the MDL.
- Any objections or motions to quash subpoenas issued out of the MDL shall be 2. filed directly into the MDL. Attorneys are permitted to make a limited appearance for the purposes of contesting a subpoena without being deemed to otherwise consent to the jurisdiction of this Court.

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3. Objections to subpoenas served before July 10, 2013 will be heard during the July 18, 2013 status conference.

SO ORDERED.

Dated this 21st day of June , 2013.

/s/ F. Dennis Saylor

F. Dennis Saylor, IV United States District Judge